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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,574	06/05/2000	Jurgen Behrens	0107-026P	7952

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EXAMINER

DAVIS, NATALIE A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 11/26/2001

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/587,574

Applicant(s)

BEHRENS ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) 24-32 and 35-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Applicant's election of Group III, claims 33-38, Species A (SEQ ID NO: 1) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL. Claims 33-34 read on the elected Group III, species A and are being examined as belonging to the elected Group III, while claims 26-32 and 35-46 are withdrawn from examination as being drawn to a non-elected invention.

### *Claim Objections*

Claims 33-34 objected to because of the following informalities: "Conductine" is misspelled and should be spelled as "conductin." Appropriate correction is required.

### *Claim Rejections - 35 USC § 101*

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 33-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a "conductin," which is non-statutory subject matter.

The claims, as written, embrace a product in nature, "conductin." The Supreme Court has ruled that the term 'manufacture' in § 101 means 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.' [See *Diamond v. Chakrabarty*, 206 USPQ 193 (1980)]. The claims as written encompass the products as they occur in nature. However, since it would appear that applicants do not intend to claim a naturally occurring product, amending the claims to recite isolated or purified conductin would obviate this rejection.

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3. Claims 33-34 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

The claims are drawn to conductin, its variations, mutants and parts thereof.

The specification discloses SEQ ID NO: 1 as conductin (p. 4), the invention relates to gene therapy for tumor diseases (p. 5), conductin causes the breakdown of  $\beta$ -catenine in SW480 cells, GSK 3b binds to conductin and concludes that conductin acts as a tumor suppressor (p. 6).

The composition lacks utility because of the following:

4. The specification does not disclose a well-established utility and does not exemplify a biological activity for the polypeptide so that any utility would be well established. The disclosure states that conductin causes the breakdown of  $\beta$ -catenine in SW480 cells and concludes that conductin acts as a tumor suppressor, but does not disclose or exemplify that the polypeptide is expressed in any disease state or not provide give any definitive evidence that conductin is a tumor suppressor and may be used in gene therapy to treat tumor diseases. Furthermore, the specification does not give any guidance or exemplify, which specific tumor diseases conductin may be used to treat or give any guidance or evidence regarding the successful treatment of any disease in a subject. Thus, there is no utility in producing conductin, a polypeptide that has no specific and/or substantial use. Thus, the claimed polypeptide lacks credible utility and the asserted utilities for the polypeptide also lack credibility. Thus, the polypeptide has no "real world" use. Since the specification gives no guidance or exemplification of utility for conductin, then no utility can be given to conductin variants, mutants and parts thereof. Accordingly, no utility can be attributed to the claimed polypeptide and, it is more likely than not that the artisan would require further experimentation on the polypeptide to reasonably confirm utility. Thus, there is no immediate apparent or "real world" utility as of the filing date.

5. In addition, there is no "real world" or substantial utility is associated with the polypeptide. In *Brenner v. Manson*, 383 U.S. 519, 535-36, 148USPQ 689, 696 (1966), the court expressed the opinion that an invention must have either an immediately apparent or fully disclosed "real world" utility. Congress intended that no patent be granted on a chemical

compound whose sole "utility" consist of its potential role as an object of use-testing, and stated, in context of the utility requirement, that "a patent is not a hunting license." "It is not a reward for the search, but compensation for its successful conclusion." Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Accordingly, the claimed invention as disclosed does not meet the requirements of 35 U.S.C. § 101 as being useful.

6. Claims 12-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### *Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Behrens, et al., (1998).

9. The claims are drawn to conductin, it variations, mutants and parts thereof and further drawn to the amino acid sequence of 1 to 840 of SEQ ID NO:1.

10. Behrens, et al. disclose the amino acid sequence 1 to 840 (SEQ ID NO:1) of conductin. Thus, the prior art reference anticipates the invention as claimed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph D  
November 16, 2001

  
ANTHONY C. CAPUTA  
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